Message Text

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ORIGIN HEW-06

INFO OCT-01 ISO-00 OES-09 AF-10 ARA-14 EA-12 EUR-12
NEA-10 SIG-03 MMO-01 IO-14 EB-08 COME-00 AGR-01
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DHEW/PHS/OASH/OIH: RFISCHER
AF:IKARAWA
EA PCLEVELAND
EUR :MPARRIS
NEA: AKKORKY
ARA-LA :SWILKINSON
----------100748 152207Z /61
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FM SECSTATE WASHDC
TO ALL DIPLOMATIC AND CONSULAR POSTS

UNCLAS STATE 206400

INFORM CONSULS

E.O. 11652: N/A

TAGS:OGEN, EIND, ETRD, SWEL, TBIO, XX

SUBJECT: FDA ADVISORY/RECALL COMMUNICATIONS
REFERENCE: BONN 10341
BERN 2717
STATE 138793

1. IT HAS BEEN BROUGHT TO FDA'S ATTENTION THAT THERE APPEARS TO BE A MISUNDERSTANDING CONCERNING THE GENERAL SUBJECT "FDA ADVISORY'S AND RECALL'S" AND THE PROTRACTED TIME FRAMES ASSOCIATED WITH THE GENERATION OF SUCH COMMUNICATIONS.
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2. IT IS THE FIRM'S RESPONSIBILITY TO NOTIFY THEIR CONSIGNEES OF THE RECALLED PRODUCT, LOT NUMBERS, A CONCISE STATEMENT OF THE REASON FOR THE RECALL, AND WHAT IS TO BE DONE WITH THE PRODUCT. THIS CONCEPT IS CLEARLY STATED IN THE FDA GUIDELINES FOR RECALLING DEFECTIVE PRODUCTS SUBJECT TO ITS JURISDICTION WHICH WERE PUBLISHED IN THE

FEDERAL REGISTER ON JUNE 16, 1978 (43FR26202).

3. FDAS COMMUNICATION TO DEPARTMENT OF STATE RE: THE NUMBER AND LOCATION OF FOREIGN CONSIGNEES MUST BE DELAYED UNTIL FDA DOES DETERMINE THAT A FIRM'S ACTION INVOLVING A PRODUCT CAN BE DEFINED AS A RECALL. OBVIOUSLY, A FIRM

CAN AND OFTEN DOES SEND A "RECALL" LETTER TO ITS CONSIGNEES SEVERAL WEEKS BEFORE FDA'S COMMUNICATION ISSUES.

4. FDA'S COMMUNICATION OFTEN SHOWS THE DATE AND METHOD THAT THE RECALLING FIRM USED TO NOTIFY ITS CONSIGNEES. IN ESSENCE, FDA IS REQUESTING THE DIPLOMATIC POST TO PERFORM AN EFFECTIVENESS CHECK TO DETERMINE IF FOREIGN CONSIGNEES ARE RECEIVING (RECALL/ADVISORY) COMMUNICATIONS FROM U.S. FIRMS SINCE FDA BELIEVES, THAT WHILE NOT FORMALLY REQUIRED BY REGULATIONS, FOREIGN RECIPIENTS ARE ENTITLED TO THE SAME PROTECTION AS SHOWN U.S. CITIZENS OF "DEFECTIVE PRODUCTS". FDA MAKES EVERY EFFORT TO DETERMINE IF FOREIGN DISTRIBUTION OF A RECALLED PRODUCT HAS OCCURRED. THE LIST OF FOREIGN CONSIGNEES AND THE VOLUME OF RECALLED PRODUCT FDA PROVIDES IN ITS RECALL COMMUNICATIONS IS OBTAINED FROM THE RECALLING FIRM. FDA TRIES TO ENSURE THE ACCURACY OF THE INFORMATION PROVIDED TO THE BEST OF ITS ABILITY. THIS PROCEDURE IN SOME CASES MAY BE TIME CONSUMING, BUT FDA BELIEVES IT IS JUSTIFIED SINCE INACCURATE INFORMATION MAY
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GIVE RISE TO ADDITIONAL PROBLEMS.

5. FDA APPRECIATES THE CONCERN ABOUT TIMELINESS. WE WILL BE REEXAMINING OUR PROCEDURES TO SEE IF OUR COMMUNICATIONS REGARDING RECALLED PRODUCTS CAN BE FURTHER EXPEDITED. VANCE

NNN

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